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# Consideration of Patient Preferences and Challenges in Storage and Access of Pharmacogenetic Test Results

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### Abstract

**Purpose**—Pharmacogenetic (PGx) testing is one of the primary drivers of personalized medicine. The use of PGx testing may provide a lifetime of benefits through tailoring drug dosing and selection of multiple medications to improve therapeutic outcomes and reduce adverse responses. We aimed to assess public interest and concerns regarding sharing and storage of PGx test results that would facilitate the re-use of PGx data across a lifetime of care.

Methods—We conducted a random-digit-dial phone survey of a sample of the U.S. public.

**Results**—We achieved an overall response rate of 42% (n=1,139). Most respondents indicated they were extremely or somewhat comfortable allowing their PGx test results to be shared with other doctors involved in their care management (90%  $\pm$  2.18%); significantly fewer respondents (74%  $\pm$  3.27%) indicated they were extremely or somewhat comfortable sharing results with their pharmacist (p<0.0001).

**Conclusion**—Patients, pharmacists, and physicians will all be critical players in the pharmacotherapy process. Patients are supportive of sharing PGx test results with physicians and pharmacists as well as personally maintaining their test results. However, further study is needed to understand which options are needed for sharing, appropriate storage and patient education about the relevance of PGx test results to promote consideration of this information by other prescribing practitioners.

## INTRODUCTION

Pharmacogenetic (PGx) testing, or the use of genetic tests to determine the optimal pharmaceutical therapy for a given individual, is considered to be one of the most promising early clinical applications arising from genomics research, with the potential to reduce the prevalence of adverse drug responses and improve efficacy.<sup>1,2</sup> A number of drugs are

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metabolized by a handful of highly polymorphic cytochrome P-450 liver enzymes.<sup>3</sup> Over a person's lifetime, they are likely to be prescribed several medications for which these and other genes have an important role in determining the rate of metabolism. Thus, the results of a PGx test will be pertinent not only to the immediate clinical situation for which testing is initially ordered but likely for future clinical encounters. As we enter the PGx era, it is imperative to consider how relevant PGx results should be managed with respect to storage and access to minimize information fragmentation and duplicate testing.<sup>4</sup> As PGx testing assay costs and their cost-effectiveness for a *single* clinical decision is a major barrier to the routine clinical application of PGx, the ability to re-use PGx data across a lifetime of care could significantly facilitate the use of such testing in routine practice.

As part of a national survey exploring public interest and attitudes toward PGx testing and specifically, ancillary information revealed by PGx testing, we asked respondents about sharing and storage of PGx test results. To our knowledge, no studies have examined this important issue essential to ensuring the lifetime benefits of PGx testing. In this paper, we discuss the benefits and limitations of several options of storage and access of PGx results informed by findings from a national public survey on PGx testing on sharing results with other physicians and pharmacists and patient management of results.

#### MATERIALS AND METHODS

#### Survey Development & Administration

As described elsewhere,<sup>5</sup> we developed a survey to explore public attitudes regarding PGx testing and the potential for ancillary information. Specifically, the final survey was comprised of several sections including personal and family experience with medications, interest in PGx testing given certain risks and uses of testing, sharing and management of test results and attitudes towards management of ancillary information revealed by PGx testing. We report here data regarding public attitudes towards sharing and management of test results [see Haga et al, 2011 and Haga et al., 2011 for other survey findings].<sup>5,6</sup>

The survey was first piloted on a random sample of the local North Carolina population before launching the national survey in fall 2009. A random digit dial sample of telephone numbers in the continental U.S. was selected for the national survey and stratified by U.S. census regions to ensure representativeness. Eligibility was based on reaching a household with an English-speaking resident, 18 years of age or older. If more than one eligible adult resided in the household, one was randomly selected.

#### **Data Analysis**

Descriptive statistical analysis was conducted to examine respondent demographics and attitudes toward sharing and management of PGx test results. For logistic regression analyses, model building was based on hypothetically-related covariates with adjustment for demographic characteristics; final variable selection was conducted using the backward selection approach. Odds ratios and corresponding 95% confidence intervals were computed; a significance level of 0.05 was used for all statistical tests. To adjust for control variables, Cochran-Mantel-Haenszel (CMH) test was applied when comparing two groups on a binary response. All analyses were conducted in SAS (Version 9.1.3 using Proc Frequency, Proc Logistic & Proc Regression).

#### RESULTS

A response rate was  $42\%^7$  was achieved in this survey. Because respondents tended to be older (51% were 55 or older), White (86%), and female (61%) to a greater extent than would be expected by chance alone, the survey data were adjusted by age (18–34, 35–54, 55 &

older), race (White & non-White), and gender based on normative data from the 2008 American Community Survey.<sup>8</sup> After post-stratification, the adjusted sample better reflected the U.S. population (51% female, 78% White, and 31% 55 or older). To further reduce the potential effect of bias, non-response adjustments were predicated on U.S. census regions.

After assessing respondents' likelihood to undergo PGx testing given a range of uses and risks, we asked respondents to indicate their level of comfort regarding sharing and management of their PGx results. In response to a question about their level of comfort in allowing test results to be shared with their other doctors, most respondents indicated that they were extremely or somewhat comfortable allowing their PGx test results to be shared with other doctors involved in their care management (90%  $\pm$  2.18%). In addition, it was found that respondents who had excellent/good health were less likely to be comfortable sharing results with other doctors (OR=0.45, p=0.007, CI [0.25–0.80]).

When asked about their level of comfort regarding sharing of their PGx test result with a pharmacist, 74% ( $\pm$  3.27%) of respondents indicated that they were extremely or somewhat comfortable sharing the results with their pharmacist. There were no respondent variables found to be significantly associated with level of comfort regarding sharing results with a pharmacist. However, after adjusting for sex, age group, level of education, and race, there was a statistically significant difference in the proportion of respondents who indicated that they were comfortable sharing their results with other doctors and the proportion of respondents who were comfortable sharing their results with their pharmacist (CMH statistic = 144.70, p < 0.0001).

When asked about how comfortable they would be keeping their PGx results in a personal record, such as stored on a card kept in the patient's wallet or purse, 70% ( $\pm$  3.54%) of respondents felt extremely or somewhat comfortable with this option for data storage. No respondent variables were associated with level of comfort in keeping their PGx results.

#### DISCUSSION

The problems associated with medical information fragmentation have been demonstrated in both primary care and specialty settings,<sup>9–11</sup> potentially resulting in adverse outcomes or delay of treatment.<sup>10</sup> In addition, missing medical information could lead to duplicate testing,<sup>4</sup> potentially resulting in delayed treatment and wasted resources. As indicated by our survey findings, the public appears comfortable having their PGx results shared with their treating physician(s), which would help avoid duplicate testing. To promote sharing of results during this early stage of use of PGx testing, it will be necessary to emphasize to patients the importance of these results for any future medical treatments prescribed and the need to inform new treating physicians about their results. In addition, physicians should begin to ask patients about previous PGx testing that may inform treatment. Similar to routinely asked questions regarding drug allergies, we could envision patients routinely queried about PGx testing for P450 enzymes and classification as a poor metabolizer (PM), intermediate metabolizer (IM), or ultra-rapid metabolizer (UM). However, given that selfreported drug allergies are often inaccurate, leading to unnecessary avoidance of drugs, 12-14 expecting patients to accurately recall and report their CYP metabolic status, much less their genotype, may be overly ambitious until the public becomes more knowledgeable about testing and the type of information provided by the test. Therefore, options are needed for appropriate storage and patient education about the relevance of PGx test results to promote consideration of this information by other prescribing practitioners. We speculate that healthy respondents may be less likely to be comfortable sharing results with other physicians due to concerns about privacy: their perceived benefit from sharing this private

information may be less than the perceived costs, e.g., with regard to potential life insurance discrimination.

Haga & Burke<sup>15</sup> proposed that PGx results be retained by either patients or stored in pharmacy databases to maximize consideration of PGx test results for new treatments. Errors in self-reporting and recall may be avoided if PGx test results were stored in a personal health record. The use of personal health records has been gradually expanding<sup>16</sup> as is physician willingness to use such records,  $^{17}$  which may improve the quality of care.  $^{18}$ Given that respondents indicated they would be comfortable maintaining their PGx results, testing laboratories could enable results to be accessible to patients in addition to sending the results to the physician's office. For example, the genetic testing company Navigenics, which up until recently provided testing directly to consumers, presented PGx test results (test interpretation not genotype) in a card format to be shared with physicians, listing the target drug, their risk of side effect, and the implications of their result. Patients would then be responsible for providing the PGx results to new providers when drugs are prescribed. Particularly in acute care situations, if this information is stored electronically on an easily accessible physical device (e.g., an insurance card) or on a secure Web site, the information could be quickly retrieved and considered when testing is not otherwise feasible. However, about one-third of participants of a PGx testing study indicated that they would not share their results with their physicians due to perceived physician disinterest, incompetence, or burden.<sup>19</sup> Other potential barriers to patient sharing may include concerns about privacy, stigmatization, discrimination, coverage and/or access to potential treatments.

Another option may be to provide access of PGx test results to pharmacists. Pharmacists already play an important role in assuring the safety of drug therapy by assessing potential adverse drug interactions when a new drug is prescribed, and by providing information about appropriate substitutions for patients with drug allergies and concomitant medications that should be avoided. The pharmacist's scope of practice has expanded to incorporate identification of alternative therapies to reduce cost or increase safety, prescribing privileges, vaccination services, and management for patients with complex drug regimens.<sup>20–26</sup> Therefore, monitoring PGx information to assure appropriate drug dosing is a natural extension of the role of pharmacists.<sup>27–29</sup> Indeed, schools of pharmacy<sup>30–32</sup> and continuing education programs<sup>33</sup> have begun to recognize the importance of education on PGx testing. A handful of studies have begun to explore the role of pharmacists and the use of PGx testing.<sup>34,35</sup>

Despite the expanded scope of pharmacy practices, the structure of an appropriate collaborative partnership between pharmacists and physicians is not yet well-defined<sup>36–39</sup>, particularly with community pharmacists.<sup>40,41</sup> Pharmacists' limited access to a patient's medical history and other test results will hinder their ability to determine the need for PGx testing and use of alternative medication. In addition, different business models of prescription filling (e.g., mail order, wholesale, retail) may not be amenable to a collaborative role between physicians and pharmacists with respect to PGx testing.

Like drug allergy information, PGx test results could be routinely stored in a patient's pharmacy record. The majority of respondents indicated they were willing to have their results shared with a pharmacist, though significantly fewer than those willing to have their results shared with other physicians, perhaps due to their limited relationship with pharmacists.<sup>42</sup> Although pharmacists, along with physicians, have been ranked as the two most trusted sources of drug information by patients,<sup>43</sup> the public's understanding of the services they may provide in addition to dispensing medication is limited,<sup>44,45</sup> possibly attributing to the lower level of comfort indicated in our survey. In addition, potential patient concerns about privacy could further account for the lower level of comfort,<sup>46</sup> particularly if

patients' recognize that their results may be placed in an electronic pharmacy dispensing system. However, since we did not ask survey respondents about electronic data storage such as EHRs, it is still speculative what factors account for the differing levels of comfort.

In the event that a drug is ordered for which a PGx test is required or strongly recommended, a pharmacist may have an obligation to alert the prescribing physician about testing and/or confirm that the test was ordered. The potential of increased medical liability due to harms caused by failure to consider PGx testing has been considered in depth elsewhere,<sup>47</sup> for which the defendants may include the drug manufacturer, insurance companies, physicians, and potentially pharmacists.

While patients and pharmacists do play an important role in the medication process, the physician remains the central agent of most medication selection and prescribing. Thus, directly influencing physician prescribing practices will be critical for ensuring the appropriate consideration of PGx factors. In particular, EHRs and their component subsystems (e.g., e-Prescribing modules) provide ideal contexts for storing PGx data and using them to influence physician prescribing behaviors. Critical to such EHR-supported, PGx-enabled personalized prescribing will be the establishment of a national health information technology infrastructure that includes the use of common data and terminology standards and the establishment of up-to-date, clinically relevant knowledge resources for how PGx results should be used to guide clinical care.<sup>48,49</sup> While there are significant challenges to establishing such an infrastructure, an EHR-based approach to storing and using PGx results is highly promising. In particular, significant progress could be made if interoperability supportive of personalized pharmacotherapy is appropriately included as a core requirement in the federal government's current efforts to finance the widespread adoption of EHRs in the United States.<sup>50</sup>

Whether through personal health records, pharmacy information systems, or EHR systems, the routine provision of PGx guidance will require the widespread availability of rigorously curated knowledge on how patients' PGx test results should influence medication selection and dosing. Currently, commercial medication knowledge bases from companies such as First DataBank, Multum, and Medi-Span are widely integrated with pharmacy information systems and EHR systems to provide pharmacists and physicians with pharmacotherapy guidance. Thus, if one or more of these commercial offerings were to begin to incorporate PGx knowledge, and if PGx testing data were to be widely collected in a standardized manner, PGx could be incorporated into routine clinical practice through the leveraging of significant existing infrastructure and processes.

In moving forward, it will be important to keep in mind that the approaches we have outlined here are complementary rather than competitive. Patients, pharmacists, and physicians are all critical players in the pharmacotherapy process, and it will be important to acknowledge that the most effective approaches will likely involve a combination of such strategies as the use of personal health records, EHRs, and the pharmacy dispensing system with a database to track PGx results. Critical will be the use of common standards to enable interoperability across these various systems, as well as appropriate privacy and security safeguards to ensure that the wishes of patients are properly honored as PGx information becomes a more widely available and increasingly important consideration in the safe and effective prescribing of pharmacotherapies.

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